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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,045	06/24/2003	Michelle M. Hanna	2072.0010003	8156
26111	7590	02/22/2006	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/602,045

Applicant(s)

HANNA, MICHELLE M.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12,85-101,115-129 and 135-148 is/are pending in the application.
- 4a) Of the above claim(s) 90,101 and 137 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12,85-89,91-100,115-129,135,136 and 138-148 is/are rejected.
- 7) ☒ Claim(s) 115,126 and 135 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/24/03; 8/12/03</u> .  | 6) <input checked="" type="checkbox"/> Other: <u>IDS 10/10/03</u> .         |

## DETAILED ACTION

### *Preliminary Remark*

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 140-150 have been renumbered claims 138-148.

### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-12, 85-97, 100, 115-129, 135-137, and 138-148; and the species election of RNA polymerase, represented by claims 1-12, 100, 115-129, and 135, in the reply filed on November 30, 2005 is acknowledged. The traversal is on the ground(s) that: a) all of the groups identified in the restriction requirement is classified in class 435, subclass 6; b) the groups were not previously restricted in the previous parent application, wherein the instant application is a divisional; and c) that searching Group I along with Groups II and III would not pose an undue search burden to the examiner for reasons set forth in a). This is not found persuasive for the following reasons.

With regard to the arguments set forth in a) and c), the arguments are not found persuasive. To simply imply that just because groups of inventions are classified in the same class and subclass (the instant case class 435, subclass 6) over simplifies the inventions classified under this classification. To expound, class 436, subclass 6, pertains to measuring or testing processes

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involving enzymes or micro-organisms; compositions or test strip therefore; or process of forming such composition or test strip (class 435), involving nucleic acid (subclass 6).

Under this general description, enormously vast and diverging inventions would be classified, such as, but not limiting to, nucleic acid hybridization, amplification, detection of all different kinds of conditions or diseases involving nucleic acid, products such as arrays, oligonucleotide blots, etc. Were Applicants' argument to be valid, as such inventions are classified in the same "class/subclass," must be searched together. However, it is clear, that such practice would result in an enormous amount of search and examination burden on the Office.

With regard to the arguments set forth in b), these arguments are ambiguous and are not found persuasive. Specifically, it is unclear whether the Applicants are arguing that the invention defined by Groups II and III are not patentably distinct or that the search burden is not present as they were previously grouped together.<sup>1</sup>

Initially, determining whether a search burden present for searching Group I, along with Groups II and III is based on whether: a) the inventions are independent or distinct<sup>2</sup>; and b) the search and examination of these independent or distinct groups would result in an undue burden. There is no prohibition against restricting claims previously identified as a single group so long as criteria a) and b) are met. In addition, the inventions defined by Groups I, II, and III were not previously searched nor examined. The reasons were already set forth as to why the inventions defined by Groups I, II, and III were independent or distinct; and that the search of the Groups were not coextensive in scope, thereby imposing an undue search burden on the Office.

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<sup>1</sup> On page 2 of the response, Applicants appear to state, "each of the three Groups [I-III] do not define independent and distinct inventions" while also stating, "even if it could be shown that the inventions were independent and distinct."

<sup>2</sup> MPEP, in discussing the restriction requirement pertaining to independent "and" distinct, clarifies that it is independent "or" distinct. (see MPEP 803, wherein it is stated, "they are either independent and or distinct"; see also MPEP 803(I)(A))

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Therefore, it is determined that the search of Groups I-III would pose an undue search burden on the Office.

The requirement is still deemed proper and is therefore made FINAL.

Claims 101, 126-129 (in-part) 135 (in-part), 138-148 (in-part) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 30, 2005.

In addition, claims 90 and 137 are withdrawn from further consideration as being drawn to non-elected invention (species, *i.e.*, DNA polymerase).

#### ***Information Disclosure Statement***

The IDS received on June 24, 2003; August 12, 2003; and October 10, 2003 are acknowledged.

Their signed PTO-1449s are enclosed herewith.

In addition, the co-pending patent applications cited in the IDS statement received on October 10, 2003 have been considered.

#### ***Drawings***

The drawings received on June 24, 2003 are acceptable.

The proposed changes to the drawings filed on June 24, 2003 are also noted.

#### ***Claim Interpretation***

Claim 1, step (d) refers to "said reiterative oligonucleotide transcripts." While no antecedent basis can be found for the term, "transcripts," it appears to be clear that the term, "reiterative

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oligonucleotide” present in step (b) provides clarity for this limitation. For added clarity, Applicants are advised to use consistent claim terms.

### ***Specification***

This application contains sequence disclosures that are encompassed by the definition for nucleotide and/or amino acid sequences set for in 37 CFR 1.82(a)(1) and (a)(2). For example, Figures 13-15 and 29 recites nucleotide sequences consisting of 10 or more contiguous nucleotides without their SEQ ID Numbers. Therefore, this application fails to comply with the requirement of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotides Sequences And/Or Amino Acid Sequence Disclosures. Applicants are advised to peruse the entire specification and identify all nucleotide sequences which consists of 10 or more contiguous nucleotides; or 4 or more amino acid residues, by their SEQ ID Numbers.

A fully responsive communication **must** contain an amendment which recites SEQ ID Numbers for nucleotide/amino acid sequences, which are embraced by the above rules, disclosed in the specification; a CFR containing the SEQ ID Numbers, a paper copy of the Sequence Listing, and a statement stating that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

### ***Claim Objections***

Claim 115 is objected to because of the following informalities: claim 115 contains a typographical error. The term, “olignucleotide” should be recited, “oligonucleotide.”

Claims 126 and 135 depend from non-elected invention (claim 101).

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 85-89, 91-100, 115-129, 135, 136, and 138-148 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps. Claim 1 recites that a “terminator” is incorporated into an oligonucleotide being synthesized from a target polynucleotide (see step b). It is known that a terminator stops or halts the extension reaction, and hence, becomes unclear how “multiple” reiterative oligonucleotides can be synthesized by the incorporation of the terminator. The claim is absolutely silent on how the multiple reiterative oligonucleotides can be synthesized. No reasonable interpretation could be made for this claim for the purpose of prior art without reading limitation into the claims from the specification.

Claims 2-12, 100, 126-129, 135, and 138-148 are indefinite by way of their dependency on claim 1.

Claim 115 is indefinite for reasons analogous discussed for claim 1. Same claim interpretation as that for claim 1 has been assumed for the purpose of prosecution.

Claims 116-129, 135, and 138-148 are indefinite by way of their dependency on claim 115.

Claim 6 is indefinite for using a trademark, “primase®.” Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name

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cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a polymerase and, accordingly, the identification/description is indefinite.

Claim 85 is indefinite for reciting the phrase, “detecting oligonucleotide comprised of repeat sequences synthesized...” because none of the previous steps recite that the target sequence had a repeat sequence. It, therefore, becomes indefinite whether the “repeat” sequence is meant to refer to “reiteratively” synthesized oligonucleotides (many oligonucleotides of the same sequences, thus a repeat), or that the actual sequence of the oligonucleotide contains a “repeat” sequence, such as TTTT, or CGCG, etc. For the purpose of prosecution, the former interpretation is assumed.

Claims 86-89, 91-100, and 135-136 are indefinite by way of their dependency on claim 85.

Claim 97 recites the limitation, “wherein immobilizing comprises...” There is insufficient antecedent basis for this limitation in the parent claim.

For the purpose of prosecution, claim 97 has been assumed to depend from claim 96.

In addition, claim 97 does not recite how hybridizing a target polynucleotide to a capture probe results in immobilization of the target polynucleotide sequence.

Claim 125 recites the limitation, “said chain terminator.” There is insufficient antecedent basis for this limitation in the claim. While its parent claim does provide the limitation, “terminator,” such generic term does not provide antecedent basis for “chain” terminator, as there are other known “terminators,” which terminates reactions, such as EDTA.

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Claim 138 is self dependent in part<sup>3</sup>.

Claims 139-148 are indefinite by way of their dependency on claim 138.

No interpretation could be made for the self-dependency of claim 138 and all claims dependent from claim 138.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 85-87, 91, 92, and 135 are rejected under 35 U.S.C. 102(b) as being anticipated by Daube et al. (Science, 1992, vol. 258, pages 1320-1324; IDS reference # AR2<sup>4</sup>).

Daube et al. disclose a method of detecting an oligonucleotide synthesized from a target sequence (see Figure 1, “template”), the method comprising:

a) hybridizing a primer with a single-stranded target sequence (an RNA primer, *see* page 1320, 3<sup>rd</sup> column, 2<sup>nd</sup> paragraph, in the phrase, “[t]he main feature is a preexisting DNA bubble flanked by double-stranded DNA, which permits a defined RNA primer complementary to the template strand...”; *see also* page 1320, 3<sup>rd</sup> column, 3<sup>rd</sup> paragraph);

b) extending said primer with a polymerase and nucleotides (page 1321, 1<sup>st</sup> column, bottom paragraph in the phrase, “[e]ither *E. coli* RNA polymerase or the holoenzyme was added to the construct with all four NTPs...”), such that said polymerase synthesizes multiple template copies (page 1321, 1<sup>st</sup> column, bottom paragraph, in the phrase, “[t]he products of the transcription reactions...”; *see also* page 1321, 2<sup>nd</sup> column to 3<sup>rd</sup> column); and

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<sup>3</sup> The indefiniteness arises only from its self dependency. Its dependency on claims 1 and 115 are definite.

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d) detecting the synthesized multiple templates on polyacrylamide gel (page 1321, 1<sup>st</sup> column, bottom paragraph), thereby clearly anticipating claims 85 and 135.

With regard to claim 86, multiple template copies are detected.

With regard to claim 87, the RNA primer is labeled on its 5' end with a radioactive label (page 1321, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph).

With regard to claim 91, the RNA primer consists of 18 nucleotides (see Figure 1).

With regard to claim 92, the synthesized oligonucleotide (i.e., the extended RNA primer) comprises 68 to 72 nucleotides (thus "comprising" 2 to 26 nucleotides; *see* page 1321, 3<sup>rd</sup> column) as well as some synthesized oligonucleotides having 36 nucleotides and 20 nucleotides (Figure 3 on page 1322).

Therefore, the invention as claimed is clearly anticipated by Daube et al.

Claims 85-87, 91, 92, 135, and 136 are rejected under 35 U.S.C. 102(b) as being anticipated by Berg et al. (U.S. Patent No. 5,837,459, issued November 17, 1998).

Berg et al. disclose a method of generating multiple reiterated oligonucleotides from a target DNA template comprising a single-stranded region, forming a complex by hybridizing to said template at a desired transcription initiation site one or more oligonucleotide (or primer) analogues capable of forming a "transcription initiation site" with said template, extending the primer with a DNA dependent RNA polymerase in the presence of nucleotide triphosphates (column 2, lines 13-21; and see Figure 1); and detecting the production of said RNAs (column 5, lines 44-46), thereby anticipating claims 85 and 135.

With regard to claim 86, multiple template copies are detected.

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<sup>4</sup> IDS received on June 24, 2003.

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With regard to claim 87, radioactively labeled dUTP is employed (column 7, lines 50-51).

With regard to claim 91, the primer (e.g., PNA) is disclosed as having a length of 5 to 60 nucleotides (column 2, lines 27-29).

With regard to claim 92, Figure 1 reveals that the synthesized oligonucleotide comprises the lengths varying from 128 nucleotides to 273 nucleotide (thus comprising 2 to about 26 nucleotides; *see* column 7, lines 57-60 and Figure 1).

With regard to claim 136, the target sequence and the primers are DNA (see Figure 7).

Therefore, the invention as claimed is clearly anticipated by Berg et al.

Claims 85, 85, 91-93, 135 and 136 are rejected under 35 U.S.C. 102(b) as being anticipated by Kacian et al. (U.S. Patent No. 5,888,729, issued March 30, 1999).

Kacian et al. disclose a method of detecting an oligonucleotide synthesized from a target sequence, the method comprising:

- a) hybridizing primer with a single-stranded target sequence (Figure 1; column 9, lines 53-55);
- b) extending said primer with a polymerase and nucleotides, such that polymerase reiteratively synthesizes a nucleotide sequence (column 9, lines 56-60; column 4, lines 46-49); and
- c) detecting the synthesized oligonucleotides (column 11, lines 40-42).

The synthesis of multiple target nucleic acid sequence is disclosed as being achieved by the promoter sequence found on the 5' region of the primer, which serves as a promoter site for the RNA polymerase which generates multiple copies of the target nucleic acids (column 4, lines 46-49, in the phrase, "extension product is then used by an RNA polymerase that recognizes the promoter

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on the promoter primer, to produce multiple RNA copies of the target sequences”), thereby clearly anticipating claims 85 and 135.

With regard to claim 86, multiple template copies are detected.

With regard to claim 91, the artisans disclose that the primer employed is generally between the lengths 10 and 100 bases or 20 and 50 bases (column 6, lines 20-22).

With regard to claim 92, the target sequence is disclosed as being a portion of *Urea plasma urealyticum* (column 11, lines 37-38), which would necessarily “comprise” 2 to about 26 nucleotides.

With regard to claim 93, the detection of the synthesized oligonucleotides is achieved by hybridization of the detection probes, which would necessarily require that said detection probes be complementary to the synthesized oligonucleotides (column 11, lines 41-42).

With regard to claim 136, the artisans explicitly state that the target sequence may be RNA or DNA (column 6, lines 2-3). The primer which would be complementary to the RNA template, therefore, must be RNA and the primer which would be complementary to the DNA template, must comprise deoxyribonucleotide sequences, (i.e., DNA).

Therefore, the invention as claimed is anticipated by Kacian et al.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 87-89 and 94-97, and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kacian et al. (U.S. Patent No. 5,888,729, issued March 30, 1999) in view of Berg et al. (U.S. Patent No. 5,837,459, issued November 17, 1998). And Nasu et al. (U.S. Patent No. 5,246,866, issued September 21, 1993).

The teachings of Kacian et al. have already been discussed above.

Kacian et al. do not disclose a method involving the incorporation of labeled nucleotides or the use of labeled primer for the detection purposes.

Kacian et al., while disclose a method of detecting the synthesized oligonucleotides, do not explicitly disclose that the detection involves fluorescently labeled moiety.

Berg et al. disclose a well known method of labeling a synthesized oligonucleotides by incorporating radioactively labeled nucleotides (column 7, lines 50-51).

Nasu et al. disclose a method of employing fluorescently labeled nucleotides in a method of detection (column 1, lines 30-36).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kacian et al. with the teachings of Berg et al. and Nasu et al., thereby arriving at the claimed invention for the following reasons.

The use of fluorescent labels in a method of labeling nucleic acid sequences (for the purpose of some kind of detection), has been well-established and practiced in the art of nucleic acid hybridization, for the well-established benefit of increased sensitivity as well as the labels being environmentally safe (*see* column 1, lines 19-21).

In addition, in a method of detecting a primer extension product, one of ordinary skill in the art would have known that there exists multiple well-known methods, such as labeling a primer with

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a label (as evidenced by Daube et al.), incorporating a labeled nucleotide to the extended nucleic acids (as evidenced by Berg et al.), or hybridization of a labeled probe (as evidenced by Kacian et al.).

Therefore, one of ordinary skill in the art would have been motivated to employ any of the well-known methods for detecting the synthesized oligonucleotides, such as that of Berg et al., wherein the one ordinary skill in the art would have been further motivated to employ fluorescent labels for the obvious benefit explicitly disclosed by Nasu et al. (environmentally safe).

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 85-89, 91-97, 100, 115-136, and 138-150 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-17 and 19-27 of copending Application No. 10/425,037 (herein, the '037 application). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The claims of the '037 application is drawn to a method involving the generation of multiple oligonucleotide transcripts from a target polynucleotide, employing a primer, a terminator, and a

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polymerase. While some of the claims involve structures, such as APC, such are narrower in their scope, which would render the claims of the instant application obvious in a species anticipating genus type claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-12, 85-89,91-97, 100, 115-136, and 138-150 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 55-105 and 113-148 of copending Application No. 10/600,581 (herein, 'the 581 application).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are slightly different in wording but obvious over each other for the following reasons.

The claims of the '581 application is drawn to a method involving the generation of multiple oligonucleotide transcripts from a target polynucleotide, employing a primer, a terminator, and a polymerase. While some of the claims involve structures, such as APC, such are narrower in their scope, which would render the claims of the instant application obvious in a species anticipating genus type claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-12, 85-89,91-97, 100, 115-136, and 138-150 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-148, and 154-159 of copending Application No. 10/607,136 (herein, the '136 application).

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Although the conflicting claims are not identical, they are not patentably distinct from each other because for the following reasons.

The claims of the '136 application is drawn to a method involving the generation of multiple oligonucleotide transcripts from a target polynucleotide, employing a primer, a terminator, and a polymerase. While some of the claims involve structures, such as APC and target site probe, such are narrower in their scope, which would render the claims of the instant application obvious in a species anticipating genus type claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-12, 85-89, 91-97, 100, 115-136, and 138-150 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 136-147 of copending Application No. 10/686,713 (herein, the '713 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because for the following reasons.

The claims of the '713 application is drawn to a method involving the generation of multiple oligonucleotide transcripts from an APC construct, wherein the method generates reiterative oligonucleotide transcripts. In some embodied claims, such as claim 139, the termination of the oligonucleotide synthesis is produced by incorporating a nucleotide analog. The claims of the '139 are narrower in their scope, which would render the claims of the instant application obvious in a species anticipating genus type claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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***Conclusion***

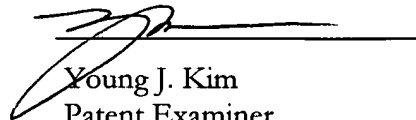
No claims are allowed.

***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim  
Patent Examiner  
Art Unit 1637  
2/17/2006

**YOUNG J. KIM  
PATENT EXAMINER**

yjk